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DEPARTMENT OF HEALTH & HUMAN SERVICES

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Public Health Service

MAY 8 1997

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

VIA FEDERAL EXPRESS

WARNING LETTER

Mr. Anton M. Straub

Owner

Nikolaus Straub Chirurgische Instrumente

Griemerstrasse 8

D-7201 Renguishausen, Germany

Dear Mr. Straub:

During an inspection of your firm located in Renguishausen, Germany on February 28, 1997, our investigator determined that your firm manufactures surgical instruments. These are devices as defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure of the quality assurance program to consist of procedures adequate to assure the approval or rejection of all in-process materials, as required by 21 CFR 820.20(a)(2). For example, procedures are not adequate to segregate in-process product from different lot numbers/catalog numbers to prevent a mixup. For example: (a) eight forceps from catalog were mixed with 80 forceps from catalog while going through a polishing operation, and (b) twenty forceps from catalog were stored in the same storage/tote bin with 70 Crawford clamps (catalog as they were awaiting an in-process inspection.
2. Failure to check, and where necessary, test for conformance with device specifications, each production run, lot or batch prior to release for distribution, and failure to hold finished devices in quarantine or otherwise adequately controlled until released, as required by 21 CFR 820.160. For example, non-conforming instruments are not separated from conforming instruments. A tray in the finished device packaging and etching area contained twelve Pean forceps, catalog two of which were etched with catalog However, the master sample and production work order showed the correct catalog number to be The remaining ten instruments in the bin had no label information

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etched on them, however, the production work order showed the twelve instruments were etched and packed for shipment on

3. Failure to implement planned and periodic audits of the quality assurance program in accordance with written procedures, as required by 21 CFR 820.20(b). For example, written procedures for conducting quality audits have not been prepared, and quality audits have not been scheduled or conducted.

This letter is not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the form FDA 483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the Food and Drug Administration. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

Given the serious nature of these violations of the Act, all devices manufactured by Nikolaus Straub Chirurgische Instrumente, Griemerstrasse 8, D-7201 Renguishausen, Germany may be detained upon entry into the United States (U.S.) until these violations are corrected.

In order to remove the devices from this detention, it will be necessary for you to provide a written response to the charges in this Warning Letter for our review. After we notify you that the response is adequate, it will be your responsibility to schedule an inspection of your facility. As soon as the inspection has taken place, and the implementation of your corrections has been verified, your products may resume entry into this country.

The FDA has received your response to the FD 483 dated March 26, 1997. The response is not adequate. More specific information may be supplied regarding the steps taken to correct all the GMP deficiencies. In response to your question, the section in the GMP for establishment of quality procedures is 21 CFR 820.20(a). The proposed submittal date for the quality audit procedures is acceptable to FDA.

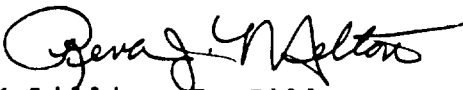
Please notify this office in writing of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make

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corrections to any underlying systems problems necessary to assure that similar violations will not recur. Please include any and all documentation to show that adequate correction has been achieved. In the case of future corrections, an estimated date of completion, and documentation showing plans for correction, should be included with your response to this letter. If documentation is not in English, please provide an English translation to facilitate our review.

Your response should be sent to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Enforcement I, General Surgery Devices Branch, 2098 Gaither Road, Rockville, Maryland 20850, to the attention of Carol Shirk.

Sincerely yours,

  
for/ Lillian J. Gill  
Director  
Office of Compliance  
Center for Devices and  
Radiological Health

Enclosure: (1) 21 CFR 820.20  
Organization

is intended to be included in the finished device.

(d) *Control number* means any distinctive combination of letters or numbers, or both, from which the complete history of the manufacture, control, packaging, and distribution of a production run, lot, or batch of finished devices can be determined.

(e) *Critical component* means any component of a critical device whose failure to perform can be reasonably expected to cause the failure of a critical device or to affect its safety or effectiveness.

(f) *Critical device* means a device that is intended for surgical implant into the body or to support or sustain life and whose failure to perform when properly used in accordance with instructions for use provided in the labeling can be reasonably expected to result in a significant injury to the user. Critical devices will be identified by the Commissioner after consultation with the Device Good Manufacturing Practice Advisory Committee authorized under section 520(f) of the act, and an illustrative list of critical devices will be available from the Center for Devices and Radiological Health, Food and Drug Administration.

(g) *Critical operation* means any operation in the manufacture of a critical device which, if improperly performed, can be reasonably expected to cause the failure of a critical device or to affect its safety or effectiveness.

(h) *Device history record* means a compilation of records containing the complete production history of a finished device.

(i) *Device master record* means a compilation of records containing the design, formulation, specifications, complete manufacturing procedures, quality assurance requirements, and labeling of a finished device.

(j) *Finished device* means a device, or any accessory to a device, which is suitable for use, whether or not packaged or labeled for commercial distribution.

(k) *Manufacturer* means any person, including any repacker and/or relabeler, who manufactures, fabricates, assembles, or processes a finished device. The term does not include any

person who only distributes a finished device.

(l) *Manufacturing material* means any material such as a cleaning agent, mold-release agent, lubricating oil, or other substance used to facilitate a manufacturing process and which is not intended by the manufacturer to be included in the finished device.

(m) *Noncritical device* means any finished device other than a critical device.

(n) *Quality assurance* means all activities necessary to assure and verify confidence in the quality of the process used to manufacture a finished device.

[43 FR 31508, July 21, 1978, as amended at 53 FR 11253, Apr. 6, 1988]

#### §820.5 Quality assurance program.

Every finished device manufacturer shall prepare and implement a quality assurance program that is appropriate to the specific device manufactured and meets the requirements of this part.

### Subpart B—Organization and Personnel

#### §820.30 Organization.

Each manufacturer shall have in place an adequate organizational structure and sufficient personnel to assure that the devices the manufacturer produces are manufactured in accordance with the requirements of this regulation. Each manufacturer shall prepare and implement quality assurance procedures adequate to assure that a formally established and documented quality assurance program is performed. Where possible, a designated individual(s) not having direct responsibility for the performance of a manufacturing operation shall be responsible for the quality assurance program.

(a) *Quality assurance program requirements.* The quality assurance program shall consist of procedures adequate to assure that the following functions are performed:

- (1) Review of production records;
- (2) Approval or rejection of all components, manufacturing materials, process materials, packaging materials, labeling, and finished devices.

approval or rejection of devices manufactured, processed, packaged, or held under contract by another company;

(3) Identifying, recommending, or providing solutions for quality assurance problems and verifying the implementation of such solutions; and

(4) Assuring that all quality assurance checks are appropriate and adequate for their purpose and are performed correctly.

(b) *Audit procedures.* Planned and periodic audits of the quality assurance program shall be implemented to verify compliance with the quality assurance program. The audits shall be performed in accordance with written procedures by appropriately trained individuals not having direct responsibilities for the matters being audited. Audit results shall be documented in written audit reports, which shall be reviewed by management having responsibility for the matters audited. Followup corrective action, including reaudit of deficient matters, shall be taken when indicated. An employee of the Food and Drug Administration, designated by the Food and Drug Administration, shall have access to the written procedures established for the audit. Upon request of such an employee, a responsible official of the manufacturer shall certify in writing that the audits of the quality assurance program required under this paragraph have been performed and documented and that any required corrective action has been taken.

#### §820.25 Personnel.

Each manufacturer shall have sufficient personnel with the necessary education, background, training, and experience to assure that all operations are correctly performed.

(a) *Personnel training.* All personnel shall have the necessary training to perform their assigned responsibilities adequately. Where training programs are necessary to assure that personnel have a thorough understanding of their jobs, such programs shall be conducted and documented. All employees shall be made aware of device defects which may occur from the improper performance of their specific jobs. Quality assurance personnel shall be made aware of defects and errors likely to be en-

countered as part of their quality assurance functions.

(b) *Personnel health and safety.* Personnel in contact with a device shall be in a healthy environment, shall be healthy, and suitably attired. Lack of cleanliness, good health, or suitable attire could adversely affect the device. Any personnel who fail a physical examination or supervision, appear to have a condition which could adversely affect the device, shall be excluded from affected areas until the condition is corrected. Personnel shall be instructed in such conditions to their supervision.

### Subpart C—Buildings

#### §820.40 Buildings.

Buildings in which manufacturing, assembling, packaging, packing, testing, or labeling operations are conducted shall be of suitable design and contain sufficient space to insure adequate cleaning, maintenance, and other necessary operations. Buildings shall provide adequate facilities designed to prevent mixups and assure orderly handling of the following: Incoming components; rejected components; sole components; in-process components; finished devices; labeled devices that have been reprocessed, worked, or repaired; equipment; patterns, tools, records, drawing prints; testing and laboratory equipment; and quarantined products.

#### §820.45 Environmental control.

Where environmental conditions at the manufacturing site could have an adverse effect on a device's fit, use, or performance, these environmental conditions shall be controlled to prevent contamination of the device and to provide proper conditions for each of the operations performed pursuant to the conditions to be considered for control are lighting, ventilation, temperature, humidity, air pressure, filtration, borne contamination, and other environmental control systems. All environmental control systems shall be periodically inspected to assure that the systems are properly functioning. Such inspections shall be documented.